

DECLARATION OF MARC SCHLAUD

I received a BS in Materials Science and Engineering with a concentration in Biomaterials from Michigan State University in May 2009. I have been working at W. L. Gore & Associates as the Quality Engineer for vascular grafts for approximately 2 years. In my role as Quality Engineer, I am charged with verifying fitness for use of devices in the vascular graft family of products. This includes design and validation of testing methods and equipment. I have also worked on design and validation of process changes for vascular graft. I validated the pressure testing machine and test method described below.

I was requested to test commercially available GORE DIASTAT® Vascular Access Grafts by measuring the diameter of samples of these grafts under pressure that increased with time. To do this, I first obtained three of these vascular access grafts from new product inventory. These grafts are available as catalog no. D06251 and have a nominal inside diameter of 6mm. The three grafts selected had Batch Codes of 7691112, 7334518 and 7416907. The GORE DIASTAT® Vascular Access Graft is made generally as described by Figures 13 and 14 of US Patent No. 5,628,782 to Myers et al., which I understand to be a reference cited by the Examiner in the prosecution of patent application S.N. 08/499,423..

To pressure test these grafts, approximately 12cm lengths were cut from the center region of the length of the obtained samples. An approximately equal length of 3/16" (4.76mm) inside diameter latex tube was inserted into each of these samples. This is done to render the graft samples water-tight, as the porous microstructure of the ePTFE grafts will not contain water under high pressure otherwise. The presence of the thin-walled latex tube has been found to have no significant effect on the pressure capabilities of ePTFE tubular vascular grafts.

Each sample was tested in turn on a Gore manufactured machine whose purpose is to test ePTFE vascular grafts under increasing pressure until the graft under test ruptures or until it reaches a maximum pressure of 450 psi, whichever occurs first. An optical micrometer was attached to the pressure test machine to measure the outside diameter of each graft under pressure. Outside diameter is measured due to the impracticality of measuring inside diameter under high pressures; the outside diameter and inside diameter are considered to change equally with increasing internal water pressure. The data are presented graphically, as a plot of diameter vs. pressure. This machine is calibrated at periodic intervals to verify its accuracy. It pressurizes the test sample using water. It first pressurizes the test sample to 10 psi and holds that pressure for ten seconds to let the test sample stabilize, and then continuously increases the pressure at a rate of 10 psi/second until the sample ruptures or until 450 psi is reached.

Copies of the graphs obtained for the three GORE DIASTAT® Vascular Access Grafts are attached as Appendix 1. All three samples were pressurized to 450 psi without bursting and with only minimal diameter change from 10 psi (outside diameter of about 8.4mm) to 450 psi (outside diameter of about 8.5mm).

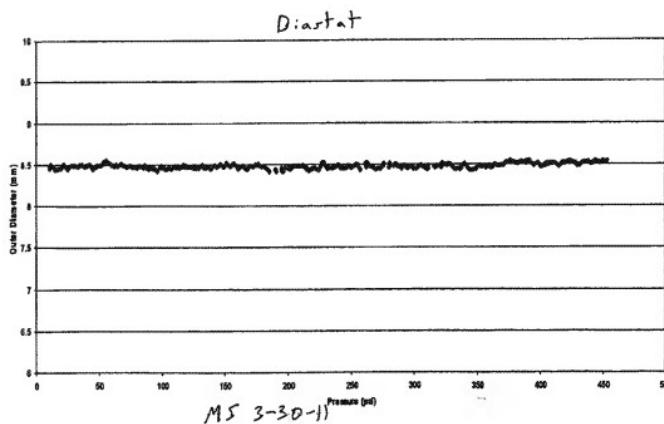
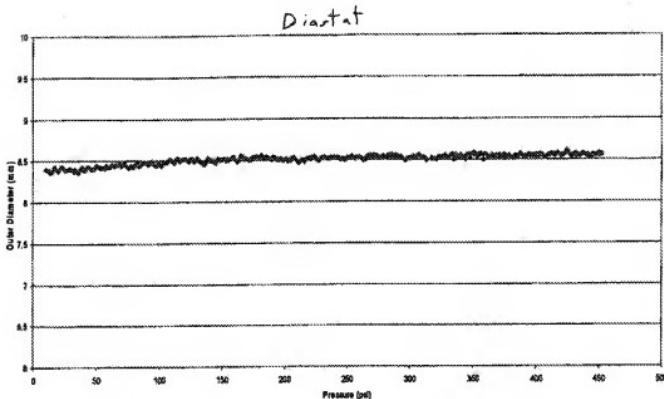


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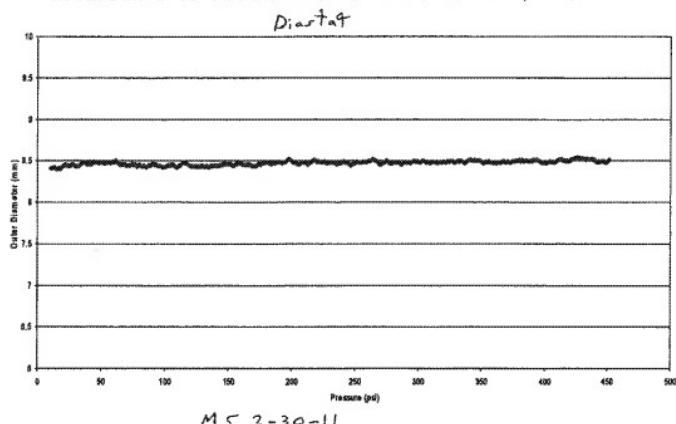
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